K090664

Section 1: 510(k) Summary

MAR 2 3 2009

Submitter:

Devon Medical Inc.
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Contact Person:

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Common Classification & Proprietary Names:

Common Names: Blood Pressure Cuff
Proprietary Name: *AccuBP Cuff*

Date Prepared:

February 18th 2009

Classification

The classification name, 21 CFR Part and Paragraph number, product code and classification of the *AccuBP Cuff.*

Classification Name	21 CFR Section	Product Code	Class
Blood Pressure Cuff	870.1120	DXQ	II

Predicate Devices

The *AccuBP Cuff* is substantially equivalent to the following:

Predicate Device	Manufacturer	510(k)#
Medline Single Patient Use Blood Pressure Cuff	Medline Industries, Inc.	K071244

The *AccuBP Cuff* has the same intended use and general construction as the predicate devices and is available in the same sizes of **Statcorp** Disposable Blood Pressure Cuff and has the same functional performance with **Statcorp** Disposable Blood Pressure Cuff.

Device Description

Per CFR 870.1120, a Blood Pressure Cuff is a device that has an inflatable bladder within, or integral to, an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The cuff is used in conjunction with an appropriate measuring device to determine a subject's blood pressure. The Devon *AccuBP Cuffs* are Latex Free.

The Devon *AccuBP Cuff* comprises tubing attached to a soft inelastic sleeve with an integrated inflatable bladder that is wrapped around the patient's limb and secured by hook and loop closure. The device tubing is connected to an appropriate non-invasive blood pressure

measurement system. The blood pressure cuffs contain no latex. Sizes include neonatal through large adult. Each cuff is packed in a sealed polyethylene (non-sterile) bag and each cuff is marked with the effective size range of limbs on which it may be used.

Attached to the end of each PVC tube are a variety of connectors for use with most monitoring systems.

The *AccuBP Cuffs* are available in the following configurations:

Five sizes for Neonatal (Neonatal #1-#5) and eight sizes for (Infant, Child, Small Adult, Adult, Adult Long, Large Adult, Large Adult Long, and Thigh)

Both Single Tube and Double Tube configuration are available for all size.

Intended Use

The Devon *AccuBP Cuff* is intended to be used in conjunction with non-invasive blood pressure monitoring systems for determination of a person's blood pressure. The device is non-sterile and disposable. It is available in neonatal, infant and adult sizes.

Technological Characteristics

The Devon *AccuBP Cuff* are identical to the **Medline** Single Patient Use Blood Pressure Cuff in design, mode of operation, and performance characteristics, all of these cuffs are configured for use with a wide variety of manual and automated sphygmomanometers.

Performance

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Devon *AccuBP Cuff.* Tests showed that the functional and operational performance characteristics including compression, pressure control, leakage, and both safety and operational parameters used when connected to inflation and measurement equipment meet standard ANSI/AAMI SP-10.

Statement of Substantial Equivalence

The *AccuBP Cuff* is substantially equivalent in technology, function, operating parameters, and intended use to Blood Pressure Cuffs that are currently commercially available and in distribution. The original devices are marked for "single-patient use only".

Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, Devon Medical Inc, concludes that the *AccuBP Cuff,* is safe and effective and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2009

Devon Medical, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K090664
Devon AccuBP Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: March 11, 2009
Received: March 13, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: The Devon AccuBP Cuff K090664

Indications for Use:

The Devon AccuBP Cuff is intended to be used in conjunction with non-invasive blood pressure monitoring systems for determination of a person's blood pressure. The device is non-sterile and disposable. It is available in neonatal, through adult sizes.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Cardiovascular

510(k) Number K090664